REMARKS

Claim 17-31 are subject to various rejections asserted in the Office Action mailed on September 17, 2007. In response to the Office Action, Applicants submit this Amendment, which amends claims 17, 20, 21, 25 and 28 and cancels claims 18, 19, 22, 24 and 31. No new matter has been added by these amendments. In view of the amendments to the claims and remarks below, Applicants respectfully request reconsideration and withdrawal of the asserted rejections.

Rejection under 35 U.S.C. § 112, First Paragraph

Claims 28-31 have been rejected under 35 U.S.C. § 112, first paragraph because the Specification purportedly fails to enable one of ordinary skill in the art of how to make and use the claimed invention. Specifically, the Office Action contends that the claims do "not reasonably provide enablement for treating all of the following diseases ...." (Office Action at page 2). However, the Office Action states that the Specification is "enabling for the treatment of androgen deficiency ...." (Office Action at page 2). Claim 28 have been amended to recite "therapeutically or prophylactically treating androgen deficiency." Since claims 29 and 30 depend from claim 28, and since claim 31 has been cancelled, in view of the amendment to claim 28, Applicants respectfully request reconsideration and withdrawal of this rejection.

Claims 28-31 have also been rejected under 35 U.S.C § 112, first paragraph, because the Office Action contends that the Specification does not enable one of ordinary skill in the art to practice "a method of curatively or prophylactically treating a mammal ...." (Office Action at pages 7-10). Claim 28, and claims 29 and 30 *vis-à-vis* the amendment to claim 28, have been amended to place "curatively" with "therapeutically".

Applicants respectfully traverse the portion of the rejection pertaining to the recitation of "prophylactically treating." Wikipedia (http://en.wikipedia.org/Prophylaxis) defines "prophylaxis" as

> (Greek *"προφύλαξις"* to guard or prevent beforehand) is any medical or public health procedure whose purpose is to prevent, rather than treat or cure, disease. Roughly, prophylactic measures are divided between *primary* prophylaxis (to

prevent the development of a disease) and *secondary* prophylaxis (whereby the disease has already developed and the patient is protected against worsening of this process).

A person of ordinary skill in the art of androgen deficiency would understand that administering androgen cannot only be used to treat androgen deficiency, but can also prevent the development of androgen deficiency (primary prophylaxis) and protect against worsening of this androgen deficiency (secondary prophylaxis). Treatment of males or females with progestogens inhibits secretion of testosterone by the testes/ovaries and consequently can induce androgen deficiency. In these cases, co-administration of androgen can provide effective primary prophylaxis against androgen deficiency. Likewise, males or females already suffering from hypoandrogenism can be protected from a worsening of the symptoms by androgen administration (secondary prophylaxis). Consequently, Applicants respectfully submit that the Specification enables one skilled in the art for both therapeutic and prophylactic treatment of androgen deficiency.

For these reasons, Applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 28-30 have been rejected under 35 U.S.C. § 112, second paragraph, as purportedly being indefinite because the claims do not recite the disease that is being treated. Claim 28 and claims 29 and 30 *vis-à-vis* the amendment to claim 28, have been amended to recite a particular disease – androgen deficiency. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Rejection under 35 U.S.C. § 102

Claims 17, 23, 26, 28, 30, and 31 have been rejected under 35 U.S.C. § 102 as purportedly being anticipated by Squibb (FR 2035786). The Office Action contends that Squibb "teaches a composition and method of use of 16α-α-D-glucoside of 16α, 17-dihydroxysteroid, namely 16α-hydroxytestosterone, in the same manner that estrogen is used in veterinary medicine." (Office Action at page 11). Claim 17, and claims 23, 26, 28, and 30 *vis-à-vis* their dependency on claim 17, have been amended to delete the recitation of 16-hydroxytestosterones. Therefore, since Squibb is limited to the above teaching and does not teach 15-hydroxytestosterone, it does not teach each and every limitation of the invention as recited in

claims 17, 23, 26, 28, and 30. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

This rejection is moot as to claim 31 because it has been cancelled.

Rejection under 35 U.S.C. § 103

Claims 18-21 have been rejected under 35 U.S.C. § 103 as purportedly being unpatentable over Upjohn Co. (GB 774,064). However, Upjohn does not discuss therapeutic applications of 15-hydroxytestosterone or provide any indication of how such substances may be administered.

For a reference to either anticipate or make obvious a claimed invention, the reference must enable one skilled in the art to make and use the invention. MPEP § 2121. The invention, as recited in amended claims 20 and 21, is directed to oral dosage units. Upjohn, however, fails to provide any indication that 15-hydroxytestosterone is (i) pharmaceutically active and (ii) orally bioavailable. Thus, the reference does not enable one skilled in the art. Consequently, the invention as recited in claims 20 and 21 would not be obvious to one of ordinary skill in the art in view of Upjohn because one of ordinary skill in the art would not know, and would not find it obvious, to incorporate 15-hydroxytestosteron in oral dosage units.

This rejection is moot as to claims 18 and 19 because these claims have been cancelled.

For these reasons, Applicants respectfully request that this rejection be reconsidered and withdrawn.

Claim 22 has been rejected under 35 U.S.C. § 103 as purportedly being unpatentable over Squibb in view of Wood (J. of Biol. Chem., 1983). This rejection is now moot because claim 22 has been cancelled. Accordingly, withdrawal of this rejection is respectfully requested.

Claims 17 and 24-31 have been rejected under 35 U.S.C. § 103 as purportedly being unpatentable over Squibb in view of Martin (WO 00/74684). Since Squibb fails to teach 15-hydroxytestosterones, it fails to teach each and every element of the claimed invention. This failure is not overcome by Martin. Accordingly, the combination of Squibb and Martin fails to teach, suggest or motivate a person of ordinary skill in the art to develop the invention as recited in claims 17 and 25-30. Accordingly, reconsideration and withdrawal of this rejection is

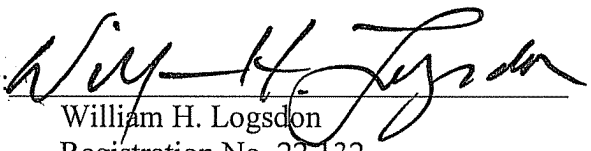
respectfully requested. This rejection is moot as to claims 24 and 31 because they have been cancelled.

Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the asserted rejections, and a Notice of Allowance directed to all pending claims. Should the Examiner like to discuss this application further, the Examiner is invited to contact the Applicants' undersigned representative at (412) 471-8815.

Respectfully submitted,

THE WEBB LAW FIRM

By: 

William H. Logsdon
Registration No. 22,132
Attorney for Applicants
700 Koppers Building
436 Seventh Avenue
Pittsburgh, Pennsylvania 15219
Telephone: 412-471-8815
Facsimile: 412-471-4094
E-mail: webblaw@webblaw.com